

Remarks

Applicant has attended to the spelling of "sequestrant" in claim 10. Please withdraw the objection to claim 10.

Applicants have amended claim 10 to clarify that the "alternative treatment" referred to in claim 7 relates to treatment with everolimus in combination with a cholesterol-lowering medication (see, e.g., page 3 of the specification, where it is discussed that alternative treatment comprises the addition of a cholesterol-lowering medication, and page 7, where it is disclosed that a cholesterol-lowering drug would be used in combination with the immunosuppressive if a C is found at position -31). Claim 10 has also been amended to recite traditional Markush language. These amendments to claim 10 are merely clarifying and do not change the scope of claim 10.

Applicants have amended the disclosure as suggested by the Examiner in order to effect incorporation by reference of GenBank Accession X04500. Thus, there is no new matter in the instant application. Please withdraw these objections.

Applicants wish to thank Examiner Pohnert for the helpful telephone discussion held November 24, 2009, in which the instant claim amendments were discussed. The Examiner and Applicants' representative agreed that the instant amendment to claims 6 and 7 overcame the outstanding enablement-based rejections. Support for the amendments to claim 6 may be found throughout the disclosure, e.g., on page 12, which discusses Applicants' findings that individuals homozygous for the T allele at position (-511) and the C allele at position (-31) of the IL-1 β gene promoter may be predisposed to larger increases in total blood cholesterol levels upon treatment with rapamycin regimens, and on page 19, which provides Table 10 having an odds ratio showing that patients treated with everolimus are 7.23 times more likely to have an increase in total blood cholesterol levels to greater than 239 mg/dl if they contain a C at position -31 of the IL-1 β gene promoter. Please withdraw the outstanding enablement-based rejection of the pending claims.

Claim 16 has been canceled in order to speed prosecution of this application. Thus, the outstanding written description-based rejection is moot.

Applicants have amended the claims to remove the parenthesis from the pending claims. Please withdraw the outstanding indefiniteness-based rejection of the pending claims.

CONCLUSION

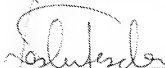
In light of the above amendments, observations and remarks, Applicants respectfully submit that the presently claimed invention satisfies 35 U.S.C. §112, and is neither disclosed nor suggested by any art of record. Accordingly, reconsideration and allowance of all claims in this application is earnestly solicited.

Applicants' undersigned attorney may be reached in our New Jersey office by telephone at (862) 778-9308. All correspondence should continue to be directed to our below-listed address.

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Respectfully submitted,



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